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**UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA**

In re: CV SCIENCES, INC. SECURITIES
LITIGATION

Case No. 2:18-cv-01602-JAD-BNW

This Document Relates To:

ALL ACTIONS

**SECOND AMENDED CLASS ACTION
COMPLAINT FOR VIOLATIONS OF
THE FEDERAL SECURITIES LAWS**

JURY TRIAL DEMANDED

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TABLE OF DEFINED TERMS AND ABBREVIATIONS

Term	Definition
CBD	Cannabidiol
CEO	Chief Executive Officer
CFO	Chief Financial Officer
Class	All persons and entities who purchased CVSI common stock in the United States or on the OTC between June 19, 2017 and 1:21 PM EST on August 20, 2018, inclusive, and who were damaged thereby
Class Period	June 19, 2017 through August 20, 2018 at 1:21 PM EST
Company	CV Sciences, Inc.
COO	Chief Operating Officer
CV Sciences	CV Sciences, Inc.
CVSI	CV Sciences, Inc.
CVSI-007	CV Sciences' lead pharmaceutical product, a chewing gum product that combines cannabidiol and nicotine for the treatment of smokeless tobacco use and addiction
Defendants	CV Sciences, Inc. and the Individual Defendants
Dowling	Defendant Joseph D. Dowling
Exchange Act	Securities Exchange Act of 1934
FDA	U.S. Food and Drug Administration
Final Rejection	The December 14, 2017 USPTO Rejection of the Patent Application for CVSI-007 for which the USPTO sent notice to the Company on December 20, 2017
First Rejection	The April 27, 2017 USPTO Rejection of the Patent Application for CVSI-007 for which the USPTO sent notice to the Company on June 6, 2017
Form 10-K	Annual Report filed with the SEC
Form 10-Q	Quarterly Report filed with the SEC
Ina	Plaintiff Richard Ina, as Trustee for The Ina Family Trust

IND	Investigational New Drug
Individual Defendants	Michael Mona, Jr.; Joseph D. Dowling; and Michael Mona, III
Lead Plaintiff	Richard Ina, as Trustee for The Ina Family Trust
Mona, III	Defendant Michael Mona, III
Mona, Jr.	Defendant Michael Mona, Jr.
NDA	New Drug Application
Patent Application	Patent Application #15/426,617 entitled “Pharmaceutical Formulations Containing Cannabidiol and Nicotine for Treating Smokeless Tobacco Addiction” for CVSI-007
Rejections	The First Rejection and Final Rejection, collectively
SEC	United States Securities and Exchange Commission
SOX	Sarbanes-Oxley Act of 2002
USPTO	United States Patent and Trademark Office

CHRONOLOGY

Date	Event
Jan. 4, 2016	CannaVEST Corp. changes its name to CV Sciences, Inc. after acquiring CanX, Inc. CV Sciences, Inc. then pivots to pharmaceutical development. ¶34.
May 16, 2016	The Company files a provisional Patent Application for CVSI-007. ¶37.
Feb. 7, 2017	The Company files a continuing Patent Application for CVSI-007. ¶40.
Apr. 27, 2017	The USPTO's First Rejection of the Patent Application for CVSI-007 occurs. ¶41.
June 6, 2017	The USPTO notifies the Company of the First Rejection of the Patent Application for CVSI-007. ¶41.
June 19, 2017	The Class Period begins when the Company, concealing the First Rejection, misleads investors when announcing its "plan for CVSI-007, the Company's patent-pending product for smokeless tobacco addiction therapy consisting of nicotine-polacrilex chewing gum in combination with synthetic cannabidiol (CBD)." ¶49. In this announcement, then-President and-CEO Mona, Jr. explained that CVSI-007 was based on the Company's " own proprietary research ." ¶49. Defendants continue to make other misleading statements throughout the Class Period which conceal the First Rejection. ¶¶51-58.
Dec. 14, 2017	The USPTO's Final Rejection of the Patent Application for CVSI-007 occurs. ¶44.
Dec. 20, 2017	The USPTO notifies the Company of the Final Rejection of the Patent Application for CVSI-007. ¶44.
Jan. 23, 2018	The Company files a notice of appeal to the Patent Trial and Appeal Board. ¶45.
Mar. 29, 2018	CFO Dowling, concealing the Final Rejection, misleads investors when he states " Our drug development segment continues to execute on our development plan to develop the only FDA-approved drug to treat smokeless tobacco use and addiction. " ¶61. He continues this ruse, stating " We have patent pending technology [.] " ¶61. Defendants will continue to make other misleading statements throughout the Class Period that conceal this Final Rejection. ¶¶63-80.
Jun. 1, 2018	The Company enters a consent judgment with the SEC for accounting fraud in which Mona, Jr. is forced to resign as CEO. ¶99.
Jun. 8, 2018	The Company announces that it has rehired Mona, Jr. as "Founder-Emeritus" and has given him a \$70,000 raise. ¶99.
Aug. 20, 2018	The Class Period ends at 1:21 PM EST when Citron Research issues a Tweet reporting on the USPTO's two Rejections of CVSI-007's Patent Application. ¶82. As a result, the Company's share price plummets \$4.99 per share, or 54.24%, to close at \$4.21 per share that same day. ¶83.

TABLE OF PERSONS AND ENTITIES

Name	Description
CannaVEST, Corp.	The Corporate Defendant's name until January 4, 2016 when it changed to its current name, "CV Sciences, Inc."
CV Sciences, Inc.	The Corporate Defendant, a life science company centered in the gray market of cannabidiols, a Delaware corporation headquartered in Las Vegas, Nevada.
Dowling, Joseph	Individual Defendant, the current CEO and CFO of CV Sciences who also serves as a Director.
FDA	The United States Food and Drug Administration
Mona, Michael III	Individual Defendant, the COO of CV Sciences who also serves as a Director.
Mona, Michael Jr.	Individual Defendant, the founder, past-CEO and a past-Director of CV Sciences. He currently serves as the "Founder-Emeritus" of the Company.
SEC	The United States Securities and Exchange Commission
USPTO	The United States Patent and Trademark Office

The allegations in this Second Amended Class Action Complaint are based on the personal knowledge of Lead Plaintiff Richard Ina, as Trustee for The Ina Family Trust (“**Lead Plaintiff**”)¹ as to Lead Plaintiff’s own acts and are based upon information and belief as to all other matters alleged herein. Lead Plaintiff’s information and belief is based upon the investigation by Lead Plaintiff’s counsel into the facts and circumstances alleged herein, including the following: (i) review and analysis of those public filings referenced herein that CV Sciences, Inc. (“**CV Sciences**,” “**CVSI**,” or the “**Company**”) made with the United States Securities and Exchange Commission (“**SEC**”); (ii) review and analysis of those press releases, analyst reports, public statements, news articles, and other publications referenced herein disseminated by or concerning CVSI and the Individual Defendants named herein (together with CV Sciences, “**Defendants**”); (iii) review and analysis of those Company conference calls, press conferences, and related statements and materials referenced herein; and (iv) review and analysis of those other documents referenced herein. Many additional facts supporting the allegations are known only to Defendants and/or are within their exclusive custody or control. Lead Plaintiff believes that additional evidence supporting the allegations will emerge after a reasonable opportunity to conduct discovery. This Second Amended Class Action Complaint is filed pursuant to Fed. R. Civ. P. 15(a)(2), as Defendants provided their written consent prior to filing.

I. NATURE AND SUMMARY OF THE ACTION

1. Subject to certain exclusions detailed herein, this is a federal securities class action on behalf of a class consisting of all persons other than Defendants who purchased Defendant CVSI common stock between June 19, 2017 through August 20, 2018 at 1:21 PM EST (the “**Class Period**”), seeking to recover damages caused by Defendants’ violations of the federal securities laws and to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the “**Exchange Act**”) and Rule 10b-5 promulgated thereunder, against the Company and certain of its top officials.

¹ All emphases are added to quotations and all internal citations and internal quotations are omitted unless otherwise noted.

2. CV Sciences is a Delaware corporation headquartered in Las Vegas, Nevada. Its stock trades on the OTCQB Marketplace (“OTCQB”) maintained by the OTC Markets Group under the ticker symbol “CVSI.”

3. CV Sciences is a life science company with two divisions — pharmaceuticals and consumer products — which operates in the gray market of cannabidiols (“CBD”). CV Sciences’ leading pharmaceutical candidate during the Class Period was **CVSI-007**, a chewing gum product that combines cannabidiol and nicotine to treat smokeless tobacco use and addiction.

4. On May 16, 2016, CVSI filed a provisional patent application², number 62/336,990, with the US Patent and Trademark Office (“USPTO”) for CVSI-007 entitled, “Pharmaceutical Formulations Containing Cannabidiol and Nicotine for Treating Smokeless Tobacco Addiction.” On February 7, 2017, CVSI filed a continuing patent application under the same title, number 15/426,617 (the “**Patent Application**”).

5. On April 27, 2017, the USPTO initially Rejected the Patent Application for CVSI-007 because it was an obvious invention and therefore “unpatentable.” The USPTO sent notice to the Company of this rejection on June 6, 2017. This was CVSI-007’s “**First Rejection.**”

6. On December 14, 2017, the USPTO affirmed its First Rejection when it issued a final rejection for the Patent Application for CVSI-007. The USPTO sent notice to the Company of this rejection on December 20, 2017. This was CVSI-007’s “**Final Rejection.**”

7. Collectively, these two USPTO decisions are referred to as the “**Rejections.**”

8. Throughout the Class Period, Defendants made statements that, *inter alia*, pumped CVSI-007 as being “*patent-pending*,” “*proprietary*,” and “*patent-protectable*.” These statements were misleading because they omitted the material adverse facts that the USPTO twice rejected CVSI-007’s Patent Application and the Company was notified of the Rejections. These omissions misled investors as to the true status of the Company’s Patent Application and its likelihood of approval, thereby significantly overstating the prospects and commercial viability of CVSI-007.

² “A provisional patent application (PPA) is a patent application that can be used by a patent applicant to secure a filing date while avoiding the costs associated with the filing and prosecution of a non-provisional patent application.” See John Calvert, *The Provisional Patent Application: What You Need to Know*, USPTO (Apr. 2010), <https://www.uspto.gov/learning-and-resources/newsletter/inventors-eye/provisional-patent-application-what-you-need-know>.

1 9. This deception is consistent with the Company's history, as its founder, Michael Mona,
 2 Jr. ("***Mona, Jr.***"), is a serial fraudster. Mona, Jr. has been charged with securities fraud by the SEC in
 3 his capacity as President and CEO of Cannavest for filing false financial reports. As a result of this
 4 latter SEC charge, the Company, and Mona, Jr. entered a consent judgment with the SEC during the
 5 Class Period that *inter alia* required Mona, Jr. to resign from the Company and barred him from serving
 6 as an officer of a public company. Thumbing its nose at this judgment, the Company soon re-hired
 7 Mona, Jr. as "Founder-Emeritus," giving him a \$70,000 raise in salary to add insult to injury.

8 10. The truth emerged at 1:21 PM EST on August 20, 2018 when Citron Research reported
 9 the USPTO's Rejections. On this news, CV Sciences' share price plummeted from a high of \$9.20 per
 10 share to close at \$4.21 per share that same day. This was an intraday decline of \$4.99 per share, or
 11 54.24%.

12 11. Defendants' misleading statements, which led to the precipitous decline in the market
 13 value of the Company's stock when the omitted facts were revealed, caused Lead Plaintiff and other
 14 Class members to suffer significant damages.

15 **II. JURISDICTION AND VENUE**

16 12. This action arises under and pursuant to Sections 10(b) and 20(a) of the Exchange Act,
 17 (15 U.S.C. §§ 78j(b), 78t(a)), and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. §
 18 240.10b-5).

19 13. This Court has jurisdiction over the action pursuant to Section 27 of the Exchange Act
 20 (15 U.S.C. § 78aa) and 28 U.S.C. § 1331.

21 14. Venue is proper in this District pursuant to § 27 of the Exchange Act, 15 U.S.C. § 78aa
 22 and 28 U.S.C. § 1391(b), as CVSI's principal place of business is in this District and certain of the acts
 23 and conduct complained of herein, including dissemination or omission of materially misleading
 24 information to the investing public, occurred in this District.

25 15. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly,
 26 used the means and instrumentalities of interstate commerce, including, but not limited to, the mails,
 27 interstate telephone communications, the Internet, and the facilities of the national securities markets.

1 **III. THE PARTIES**

2 16. Plaintiff Richard Ina (“**Ina**”), as Trustee for The Ina Family Trust, purchased CVSI
3 common stock at artificially inflated prices during the Class Period and was damaged thereby when the
4 truth was revealed. *See* ECF No. 5-4.

5 17. Defendant CV Sciences, Inc. is a Delaware Corporation with a principle executive office
6 at 2688 South Rainbow Boulevard, Suite B, Las Vegas, NV 89146. CVSI trades on the OTCQB market
7 under the ticker symbol “CVSI.”

8 18. Individual Defendant Michael Moná, Jr. (“**Moná, Jr.**”), the Company’s founder, served
9 as Chief Executive Officer (“**CEO**”), and a Director of the Company from January 2013 until May
10 2018. Since May 2018, Moná, Jr. has served as Founder Emeritus. Moná, Jr. made or had authority
11 over the content, and how to communicate it, of the misleading statements and omissions set forth
12 herein at ¶¶49, 51, 53, 58, 67, 69 and is liable for those misleading statements and omissions. Moná, Jr.
13 is also liable as a control person of CVSI within the meaning of §20(a) of the Exchange Act.

14 19. Individual Defendant Joseph D. Dowling (“**Dowling**”) has served as the Company’s
15 CEO since May 2018 and has served as Chief Financial Officer (“**CFO**”) since June 2014. Dowling
16 has served as a director of the Company since August 2018. Dowling made or had authority over the
17 content, and how to communicate it, of the misleading statements and omissions set forth herein at ¶¶-
18 51, 55, 57, 58, 61, 63, 65, 67, 69, 71, 73, 75, 77, 78 and is liable for those misleading statements and
19 omissions. Dowling is also liable as a control person of CVSI within the meaning of §20(a) of the
20 Exchange Act.

21 20. Individual Defendant Michael Moná, III (“**Moná, III**”) has served as the Company’s
22 Chief Operating Officer (“**COO**”) since March 2017 and a Director since May 2016. Moná, III made
23 or had authority over the content, and how to communicate it, of the misleading statements and
24 omissions set forth herein at ¶67 and is liable for those misleading statements and omissions. Moná, III
25 is also liable as a control person of CVSI within the meaning of §20(a) of the Exchange Act.

26 21. Collectively, Moná, Jr., Dowling, and Moná, III are herein referred to as the “**Individual**
27 **Defendants.**”
28

IV. SUBSTANTIVE ALLEGATIONS

A. The Drug Development Process

22. Commercially viable pharmaceutical products must be approved by both the U.S. Patent and Trademark Office and the U.S. Food and Drug Administration (“FDA”). *See* Dennis S. Fernandez *et al.*, *The Interface of Patents with the Regulatory Drug Approval Process and How Resulting Interplay Can Affect Market Entry*, IP Handbook of Best Practices (2007), <http://www.iphandbook.org/handbook/ch10/p09/>.

23. A patent is the grant of a property right to the inventor, issued by the USPTO, to exclude others from making, using, offering for sale or importing the invention into the United States. *See* USPTO, *General Information Concerning Patents* (Oct. 2015), <https://www.uspto.gov/patents-getting-started/general-information-concerning-patents#heading-2>. Therefore, a patent guarantees that the intellectual property underlying the invention is proprietary; thus, *the invention (and its underlying “intellectual property”) is not proprietary absent a patent.*

24. Generally, the term of a new patent is 20 years from the date on which the application for the patent was filed in the United States. *Id.* Once a patent application has been accepted as complete, it is assigned for examination. *Id.* A patent examiner reviews its contents to determine if the application meets certain legal requirements. *Id.* One of these requirements, as articulated in 35 U.S.C. § 103, is that the patent application not be obvious. The USPTO explains:

Even if the subject matter sought to be patented is not exactly shown by the prior art, and involves one or more differences over the most nearly similar thing already known, *a patent may still be refused if the differences would be obvious. The subject matter sought to be patented must be sufficiently different from what has been used or described before that it may be said to be non-obvious to a person having ordinary skill in the area of technology related to the invention.* For example, the substitution of one color for another, or changes in size, are ordinarily not patentable.

Id.

25. The applicant is notified in writing of the examiner’s decision by an Office “action,” which is normally mailed to the attorney or agent of record delegated power of attorney by the patent applicant. *Id.* If this action includes a patent rejection, the Office must explain the rejection to help the patent applicant determine “the propriety of continuing the prosecution of his or her application.” *Id.*

26. If the patent applicant disagrees with this rejection, the applicant must request reconsideration in writing and must distinctly and specifically point out the supposed errors in the examiner's Office action. *Id.* Interviews with examiners are often arranged during this stage. *Id.*

27. "After reply by the applicant, the application will be reconsidered, and the applicant will be notified as to the status of the claims—that is, whether the claims are rejected, or objected to, or whether the claims are allowed, in the same manner as after the first examination. ***The second Office action usually will be made final.***" *Id.* Because it is final, the applicant's ability to further amend his or her application is restricted. If the applicant wants to challenge this decision, the applicant must make an appeal to the Patent Trial and Appeal Board. *Id.*

28. ***The Patent Trial and Appeal Board will typically affirm this decision.*** A comprehensive study from 1996 to 2005 found that only 41.4% of USPTO decisions that finally reject a patent are overturned by the Patent Trial and Appeal Board. *See* Michael Carley, Deepak Hegde, Alan Marco, *What Is the Probability of Receiving a U.S. Patent?* 17 Yale J. L. & Tech. 203, 209 (2015). In recent years, the Patent Trial and Appeal Board's affirmation rate has increased. In Fiscal Years 2013 to 2018, the percentage of USPTO decisions that finally rejected patent applications that were overturned by the Patent Trial and Appeal Board decreased to 39.3% (2013), 31.3% (2014), 28.9% (2015), 28.6% (2016), 29.5% (2017), and 28.3% (2018). *See* USPTO, *Appeal and Interference Statistics*, <https://www.uspto.gov/patents-application-process/patent-trial-and-appeal-board/statistics>.

29. Intellectual property experts note "***innovating companies should file patents for their products before seeking FDA approval for them***" because, *inter alia*:

[P]atents are important IP (intellectual property) safeguards. If an innovating company were to begin the FDA process before filing a PTO application, another company could patent the invention before them. The innovating company would either have to license the biopharmaceutical from the other company (losing royalties, market exclusivity, and company value in the process) or abandon the FDA process altogether and forfeit millions spent in research and development.

See Dennis S. Fernandez et al., *The Interface of Patents with the Regulatory Drug Approval Process and How Resulting Interplay Can Affect Market Entry*, IP Handbook of Best Practices (2007), <http://www.iphandbook.org/handbook/ch10/p09/>.

30. It would be “*tremendously unwise to proceed sans patents*” because “[n]o patent means the generic can enter the market as soon as the FDA exclusivity period expires, and having a patent can extend the exclusivity period to the end of the patent term, often years later.” See Angélique McCal and Gene Quinn, *The FDA process, patents, and market exclusivity*, IPWatchdog (Mar. 12, 2017), <http://www.ipwatchdog.com/2017/03/12/fda-process-patents-market-exclusivity/id=79305/>. As such “patent protection should be sought early in R&D because once the drug is commercially successful, it’s too late to generate considerable revenues since generics can make their way onto the scene.” *Id.*

31. Once a drug developer secures patent rights, the drug developer typically submits an Investigational New Drug (“**IND**”) Application to the FDA. See Dennis S. Fernandez *et al.*, *The Interface of Patents with the Regulatory Drug Approval Process and How Resulting Interplay Can Affect Market Entry*, IP Handbook of Best Practices (2007), <http://www.iphandbook.org/handbook/ch10/p09/>. In effect, this application seeks authorization to administer the drug to humans in clinical trials. See FDA, *Information for Sponsor-Investigators Submitting Investigational New Drug Applications*, <https://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplication/ucm071098.htm>.

32. When the drug developer believes that enough evidence on the drug’s safety and effectiveness has been obtained to meet the FDA’s requirements for marketing approval, it submits a New Drug Application (“**NDA**”) to the FDA. See FDA, *Types of Applications*, <https://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/default.htm>. The application must contain data from specific technical viewpoints for review, including chemistry, pharmacology, medical, biopharmaceutics, and statistics. *Id.* If the NDA is approved, the product may be marketed in the United States. *Id.*

B. The Company And Its Business

33. CV Sciences, a life science company centered in the gray market of cannabidiols, is a Delaware corporation headquartered in Las Vegas, Nevada. Its stock trades on the OTCQB Marketplace maintained by the OTC Markets Group under the ticker symbol “CVSI.” CVSI Annual Report, Form 10-K, 1 (Mar. 30, 2018).

34. CV Sciences was initially a consumer products company known as “CannaVEST Corporation” focused on “manufacturing, marketing and selling plant-based CBD products to a range of market sectors.” *See* CVSI, Michael Moná, Jr.’s Letter to Shareholders (Sept. 19, 2016). CannaVEST changed its name to CV Sciences on January 4, 2016 soon after it acquired CanX, Inc. *Id.* Then-President and-CEO Moná, Jr. explained:

[W]e announced the acquisition of CanX Inc., to pivot our strategic focus from leading the market of hemp-derived cannabidiol (“CBD”) oil products into an expansive pharmaceutical company focused on the development and commercialization of innovative medicines. Given our already established position as a market leader in CBD consumer products, the shift in our corporate strategy to include drug development was a critical move because it positioned CV Sciences as a life science company, addressed sizeable multi-billion dollar markets and expanded our potential to increase shareholder value.

Id. Thereafter, CVSI created a pharmaceutical division tasked with developing “synthetically-formulated cannabidiol-based medicine.” CVSI Annual Report, Form 10-K, 1 (Mar. 30, 2018). This division would focus on “developing and commercializing novel therapeutics utilizing synthetic CBD to treat smokeless tobacco (e.g. chewing tobacco) use and addiction.” *Id.*

35. Moná, Jr. stoked investor interest in this product category, noting:

Nicotine is the largest drug addiction problem worldwide and represents a significant opportunity to develop an effective treatment for this addiction. According to Statista, there was approximately \$5.3 billion in retail sales of smokeless tobacco products in 2014, and approximately 1.3 billion units of smokeless tobacco products were sold during that time. Smokeless tobacco addiction is an unmet need that addresses a massive market opportunity, and we believe that our initial drug candidate to treat smokeless tobacco addiction will dramatically improve patient outcomes for millions.

See CVSI, Current Report (Form 8-K), Ex. 99.1 (Sept. 22, 2016). He explained, “[g]iven that there are no FDA-approved drugs to treat smokeless tobacco addiction and that the FDA has approved numerous nicotine replacement therapy drugs (NRTs), we believe that our drug candidate will be extremely well-received in the market.” *Id.*

36. To capitalize on this massive opportunity, CVSI’s pharmaceutical division was tasked with only one goal — to develop the Company’s lead pharmaceutical product, “CVSI-007,” a chewing gum that combined CBD and nicotine for the treatment of smokeless tobacco use and addiction. *Id.*

37. On May 16, 2016, the Company filed a provisional patent application, number 62/336,990, entitled, “Pharmaceutical Formulations Containing Cannabidiol And Nicotine For Treating Smokeless Tobacco Addiction.” U.S. Patent Application No. 62/336,990, Unpublished (filing date May 16, 2016) (CV Sciences, Inc., applicant).

38. Then-President and-CEO Mona, Jr. explained, “[w]e have a patent pending on the technology [.]” *See* CVSI, Current Report (Form 8-K), Ex. 99.1 (Sept. 22, 2016). In this letter, Mona, Jr. told investors specifics about the drug development process, *including the precise status of its patent application*. A screenshot of this drug development plan is included below, with relevant portions outlined in blue:

Accelerated Progress in Drug Development

Thus far, our drug development program has achieved great success. We have been hitting our milestones in great strides and are excited to share our progress in the following areas:

- Design of initial drug candidate ✓
- Filing of initial patent (provisional) ✓
- Formulation and production of proprietary CGMP synthetic CBD ✓
- In-vitro assay of CBD as an MAO inhibitor ✓
- Finalization of internal drug development program ✓
- Establishment of drug development team ✓
- Selection of contract manufacturer for drug candidate -in progress
- Preclinical animal studies: safety -in progress
- Preparation for pre-IND meeting - ongoing
- Preparation for IND filing -ongoing

We have been progressing well with our preclinical efforts and will keep you updated on all the latest developments as we plan on commencing our human studies in 2017.

39. In this letter, the Company and Mona, Jr. noted that the Company had filed its initial, provisional patent in 2016 and they added that the Company would keep investors “*updated on all of the latest developments as we plan on commencing human studies in 2017.*” *Id.* at 2. They even included a mostly completed checklist. *Id.* ***Defendants would therefore need to secure a Patent for CVSI-007 to continue making measurable progress in CVSI-007’s development.***

40. On February 7, 2017, CVSI filed a continuing patent application number 15/426,617 with the USPTO under the same title. U.S. Patent Application No. 15/426,617, Publication No. 2017-0326126 A1 (published Nov. 16, 2017) (CV Sciences, Inc., applicant).

C. The USPTO Repeatedly Rejects CVSI-007's Patent Application

41. On April 27, 2017, *the status of CVSI-007's pending Patent Application changed* when the USPTO made its First Rejection of the Patent Application for being obvious. *See* USPTO, *Patent Application No. 15/426,617 Transaction History*, <https://portal.uspto.gov/pair/PublicPair>. On June 6, 2017, it mailed and emailed CVSI a letter indicating this action and the related status change of CVSI's Patent Application. *See* USPTO, *Patent Application No. 15/426,617 Transaction History*. The USPTO stated that CVSI-007 was "*unpatentable*" because "*it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention.*" *See* USPTO, *Patent Application No. 15/426,617 Non-Final Rejection*, 9-14 (June 6, 2017), <https://portal.uspto.gov/pair/PublicPair>.

42. Despite Mona, Jr.'s earlier guarantee that Defendants would keep investors "updated on all of the latest developments" regarding CVSI-007's preclinical progress (*supra* ¶¶38-39), Defendants concealed the USPTO's decision from investors.

43. On August 11, 2017, Defendants submitted a formal response to this action. *See* USPTO, *Patent Application No. 15/426,617 Applicant Arguments/Remarks Made in an Amendment* (Aug. 11, 2017), <https://portal.uspto.gov/pair/PublicPair>. Twice thereafter, on August 23, 2017 and August 30, 2017, CVSI initiated telephonic interview contact with the USPTO in reference to CVSI-007's application. *See* USPTO, *Patent Application No. 15/426,617 Transaction History*, <https://portal.uspto.gov/pair/PublicPair>. Defendants never disclosed these actions to investors.

44. On December 14, 2017, *the status of CVSI-007's patent changed again* when the USPTO made its Final Rejection of the Patent for being obvious. *See* USPTO, *Patent Application No. 15/426,617 Transaction History*, <https://portal.uspto.gov/pair/PublicPair>. On December 20, 2017, it mailed and emailed CVSI a letter indicating this decision and the related status change of CVSI's Patent Application. *See* USPTO, *Patent Application No. 15/426,617 Final Rejection* (Dec. 20, 2017), <https://portal.uspto.gov/pair/PublicPair>. In this rejection, the USPTO cited 35 U.S.C. § 103 (the relevant patent law) to explain why CVSI-007's patent was unpatentable:

A patent for a claimed invention may not be obtained, notwithstanding that the claimed invention is not identically disclosed as set forth in section 102 of this title, if the differences between the claimed invention and the prior art are such

that the claimed invention as a whole would have been *obvious* before the effective filing date of the claimed invention to a person having ordinary skill in the art which the claimed invention pertains.

Id. at 4. In reaching this conclusion, the USPTO noted that it read Defendants’ formal response to its First Rejection and acknowledged the arguments presented, “*but does not consider them persuasive.*”

Id. at 10. Again, Defendants concealed this final Patent rejection from investors.

45. On January 23, 2018, the Company filed a notice of appeal to the Patent Trial and Appeal Board. *See* USPTO, *Patent Application No. 15/426,617 Notice of Appeal* (Jan. 23, 2018), <https://portal.uspto.gov/pair/PublicPair>. On February 15, 2018 it filed its related appeal brief. *See* USPTO, *Patent Application No. 15/426,617 Appeal Brief Filed* (Feb. 15, 2018), <https://portal.uspto.gov/pair/PublicPair>. Consistent with past practice, Defendants concealed this from investors.

D. Defendants Make Misleading Statements Concerning CVSI-007

46. “A fact is a thing ‘done or existing’ or an ‘actual happening.’” *Omnicare, Inc. v. Laborers Dist. Council Const. Indus. Pension Fund*, 135 S. Ct. 1318, 1325 (2015). It is unlawful to (1) “make any *untrue* statement of a material fact” or (2) “omit to state a material fact necessary in order to make the statements made, in the light of the circumstances under which they were made, not *misleading*[.]” *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 37 (2011) (quoting 17 C.F.R. § 240.10b-5(b)). A statement or omission is misleading “if it would give a reasonable investor the impression of a state of affairs that differs in a material way from the one that actually exists.” *Berson v. Applied Signal Tech., Inc.*, 527 F.3d 982, 985 (9th Cir. 2008). “[S]ome statements, although literally accurate, can become, through their context and manner of presentation, devices which mislead investors.” *Miller v. Thane Int’l, Inc.*, 519 F.3d 879, 886 (9th Cir. 2008).

47. “An opinion is a belief, a view, or a sentiment which the mind forms of persons or things.” *Omnicare, Inc.*, 135 S. Ct. at 1325. For an omission to make an opinion misleading, “[t]he investor must identify particular (and material) facts going to the basis for the issuer’s opinion—facts about the inquiry the issuer did or did not conduct or the knowledge it did or did not have—whose omission makes the opinion statement at issue misleading to a reasonable person reading the statement fairly and in context.” *Id.* at 1332. “Whether an omission makes an expression of opinion misleading

always depends on the context [.]” *City of Dearborn Heights Act 345 Police & Fire Ret. Sys. v. Align Tech., Inc.*, 856 F.3d 605, 615 (9th Cir. 2017). Furthermore, opinions can give rise to liability if they contain embedded statements of untrue facts.” *See Omnicare*, 135 S. Ct. at 1321.

48. Defendants’ concealment of the USPTO’s Rejections rendered their Class Period statements concerning CVSI-007 materially misleading.³

1. Defendants Conceal The USPTO’s Initial Rejection Of CVSI-007

49. The Class Period begins on June 19, 2017, when CV Sciences announced its “plan for CVSI-007, the Company’s ***patent-pending product*** for smokeless tobacco addiction therapy consisting of nicotine-polacrilex chewing gum in combination with synthetic cannabidiol (CBD).” *See* CVSI, Press Release, *CV Sciences, Inc. Announces Commencement of IND preparation immediately following Pre-IND Meeting With FDA* (June 19, 2017).⁴ In this announcement, then-President and-CEO Mona, Jr. noted that CVSI-007 was based on the Company’s “***own proprietary research***.” *Id.*

50. These statements were misleading when made because the Company and Mona, Jr. knowingly and/or recklessly made the statements while omitting the following facts:

- a. The USPTO issued the First Rejection of CVSI-007’s Patent Application and the Company was notified of the First Rejection, which omissions misled investors as to the true status of the Company’s Patent Application and its diminished likelihood of approval; and
- b. The Company lacked proprietary research as evidenced by the USPTO’s First Rejection which determined that CVSI-007 was “unpatentable” because it was an obvious invention.

51. On August 11, 2017 in its Quarterly Report for the Second Quarter of 2017, which was signed by then-President and-CEO Mona, Jr. and CFO Dowling, the Company stated, “Our specialty pharmaceutical business segment is developing synthetic cannabinoids to treat a range of medical

³ In this section, the actionable statements being challenged as misleading are those statements that are ***bolded and italicized***.

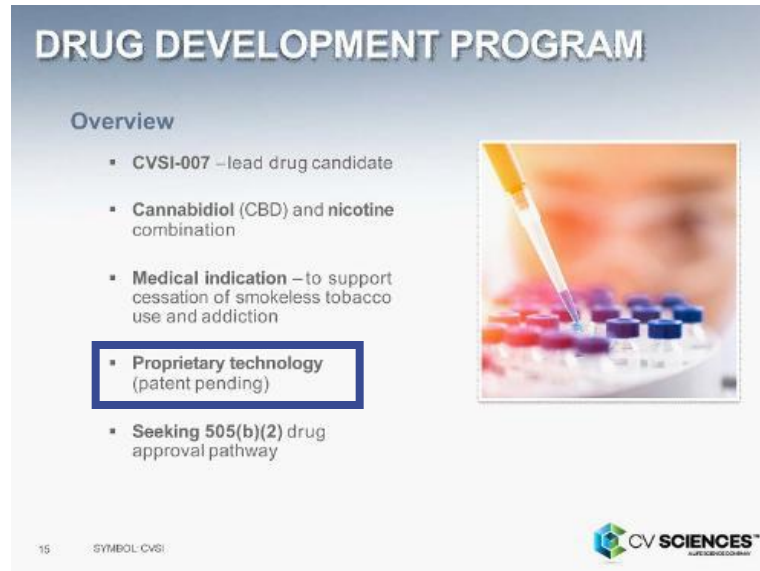
⁴ These pre-IND meetings are part of a commonplace consultation program available to potential IND holders to facilitate early communications with the FDA regarding an IND. *See* University of Virginia, Pre-IND Process, <https://research.med.virginia.edu/clinicalresearch/protocol-manager/set-up-study/compliance/investigational-new-drug-ind/pre-ind-process/>.

1 conditions. *The Company's product candidates are based on proprietary formulations, processes and*
 2 *technology that we believe are patent-protectable*, and we plan to vigorously pursue patent protection
 3 on the Company's two drug candidates." See CVSI, Quarterly Report (Form 10-Q), 24 (Aug. 11,
 4 2017).

5 52. This statement was misleading when made because the Company, Mona, Jr, and
 6 Dowling knowingly and/or recklessly made the statement while omitting the following facts:

- 7 a. The Company lacked proprietary formulations, processes, and technology as
 8 evidenced by the USPTO's First Rejection which determined that CVSI-007 was
 9 "unpatentable" because it was an obvious invention; and
- 10 b. The USPTO issued the First Rejection of CVSI-007's Patent Application and the
 11 Company was notified of the First Rejection, which omissions rendered the
 12 Company, Mona Jr., and Dowling's opinion that they believed CVSI-007 was
 13 "patent-protectable" misleading to a reasonable person reading the statement fairly
 14 and in context.

15 53. On September 12, 2017, the Company hosted a shareholder presentation that included
 16 published materials. See CVSI, Current Report (Form 8-K), Ex. 99.1 (Sept. 14, 2017). These materials
 17 were signed by then-President and-CEO Mona, Jr and they included a PowerPoint slide (included below
 18 with the relevant misleading portion highlighted by the blue box) that touted CVSI's "*proprietary*
 19 *technology*" for its "*patent pending*" drug candidate.



54. These statements were misleading when made because the Company and Mona, Jr. knowingly and/or recklessly made the statements while omitting the following facts:

- a. The USPTO issued the First Rejection of CVSI-007's Patent Application and the Company was notified of the First Rejection, which omissions misled investors as to the true status of the Company's Patent Application and its diminished likelihood of approval; and
- b. The Company lacked proprietary technology as evidenced by the USPTO's First Rejection which determined that CVSI-007 was "unpatentable" because it was an obvious invention.

55. On November 8, 2017, the Company and CFO Dowling stated:

Just a couple more slides and then we'll have Q&A. A few brief comments on our drug development operating segment. This slide provides a bullet point summary of our drug development program for CVSI-007, our lead drug candidate. Our development program is a combination therapy utilizing cannabidiol and nicotine for the medical indication of treating smokeless tobacco use and addiction. **We have patent pending technology** and we fully expect this will be developed under 505(b)(2) and accelerated approval pathway under the Federal Food, Drug, and Cosmetic Act.

See CVSI, Q3 2017 Earnings Call, 2-3 (Nov. 8, 2017) (transcript on file with Bloomberg, L.P.).

56. This statement was misleading when made because the Company and Dowling knowingly and/or recklessly made the statement while omitting the following facts:

a. The USPTO issued the First Rejection of CVSI-007's Patent Application and the Company was notified of the First Rejection, which omissions misled investors as to the true status of the Company's Patent Application and its diminished likelihood of approval.

57. In the PowerPoint presentation that accompanied this Earnings Call, the Company and Dowling used a nearly identical slide from its earlier presentation on September 12, 2017 (*supra* ¶53). See CVSI, Investor Presentation Q3 2017, 13 (Nov. 8, 2017). This slide again touted CVSI's "*proprietary technology*" for its "*patent pending*" drug candidate. *Id.* This statement by the company and Dowling was misleading for the same reasons mentioned above. *Supra* ¶54.

58. The Company repeated its exact statement from its 2017 Second Quarter Report (*supra* ¶51) in its 2017 Third Quarter Report, which was signed by then-President and-CEO Michael Mona, Jr. and CFO Joseph D. Dowling. See CVSI, Quarterly Report (Form 10-Q), 24 (Nov. 8, 2017). This statement by the Company, Mona, Jr., and Dowling was misleading for the same reasons as mentioned above. *Supra* ¶52.

59. In summary, the statements in ¶¶49-58 were materially misleading when made because Defendants (except Mona, III) failed to disclose the material adverse fact that the USPTO rejected CVSI-007's Patent Application for being obvious and therefore "unpatentable." As a result, CVSI significantly overstated the commercial viability of CVSI-007 due to the reduced likelihood that CVSI's Patent Application would be approved.

2. Defendants Conceal The USPTO's Final Rejection Of CVSI-007

60. Defendants continued to make misleading statements after learning that the USPTO had made a Final Rejection of the Patent on December 20, 2017. *Supra* ¶44.

61. On March 29, 2018, CFO Dowling continued pumping the Patent Application, even though it had now been finally rejected by the USPTO. In a conference call with investors, he stated:

Our drug development segment continues to execute on our development plan to develop the only FDA-approved drug to treat smokeless tobacco use and addiction. We are a life science company, dedicated to the advancement of science, health and well-being and education and safety for our customers and patients in both our consumer product and drug development operating segments.

So now, just a few words about our drug development division and then the presentation will be finished. This slide provides a bullet point summary of our drug development program for CVSI-007, our lead drug candidate. Our development program is a combination therapy utilizing cannabidiol and nicotine for the medical indication of treating smokeless tobacco use and addiction. **We have patent pending technology** and we fully expect this will be developed under a 505(b)(2) accelerated drug approval pathway.

See CVSI, Q4 2017 Earnings Call, 2-4 (Mar. 29, 2018) (transcript on file with Bloomberg, L.P.).

62. These statements were misleading when made because the Company and Dowling knowingly and/or recklessly made the statements while omitting the following facts:

- a. The USPTO issued the Final Rejection of CVSI-007's Patent Application and the Company was notified of the Final Rejection, which omissions misled investors as to the true status of the Company's Patent Application, especially considering the diminished likelihood of approval associated with the Final Rejection (*supra* ¶28); and
- b. The Company was not executing its drug development plan, which included the patenting of CVSI-007 (*supra* ¶39), given the USPTO's Final Rejection of CVSI-007's Patent Application and the Company's receipt of this Final Rejection.

63. In the PowerPoint presentation that accompanied this Earnings Call, the Company and Dowling used a nearly identical slide from its earlier presentation on September 12, 2017 (*supra* ¶53). See CVSI, Investor Presentation Annual Report, 15 (Mar. 29, 2018). This touted CVSI's "**proprietary technology**" for its "**patent pending**" drug candidate.

64. These statements were misleading when made because the Company and Dowling knowingly and/or recklessly made the statements while omitting the following facts:

- a. The USPTO issued the Final Rejection of CVSI-007's Patent Application and the Company was notified of the Final Rejection, which omissions misled investors as to the true status of the Company's Patent Application, especially considering the diminished likelihood of approval associated with the Final Rejection (*supra* ¶28).
- b. The Company lacked proprietary technology as evidenced by the USPTO's Final Rejection which affirmed that CVSI-007 was "unpatentable" because it was an obvious invention.

65. That very same day, the Company announced, “Strong Progress in Drug Development Division (original emphasis omitted) including preclinical progress with **CVSI-007, the Company’s patent pending synthetic-based cannabidiol**[.]” See Press Release, *CV Sciences, Inc. Reports Fourth Quarter and Full Year 2017 Financial Results* (Mar. 29, 2018). In this announcement, CFO Dowling said “[o]n the drug development side, we continue to make steady progress in advancing CVSI-007 - our proprietary lead drug candidate - which addresses the multibillion dollar smokeless tobacco use and addiction market.” *Id.*

66. These statements were misleading when made because the Company and Dowling knowingly and/or recklessly made the statements while omitting the following facts:

- a. The USPTO issued the Final Rejection of CVSI-007’s Patent Application and the Company was notified of the Final Rejection, which omissions misled investors as to the true status of the Company’s Patent Application, especially considering the diminished likelihood of approval associated with the Final Rejection (*supra* ¶28);
- b. The Company lacked a proprietary lead drug candidate as evidenced by the USPTO’s Final Rejection which affirmed that CVSI-007 was “unpatentable” because it was an obvious invention;
- c. The Company was not continuing to make steady progress in executing its drug development plan, which included the patenting of CVSI-007 (*supra* ¶39), given the USPTO’s Final Rejection of CVSI-007’s Patent Application and the Company’s receipt of this Final Rejection; and,
- d. As a result, the Company’s prospects for gaining market share in the “multibillion dollar smokeless tobacco use and addiction market” were overstated given the diminished likelihood that the Company would ever be able to obtain a patent.

67. On March 30, 2018, the Company made a similar statement in its Annual Report which was signed by then-President and-CEO Michael Mona, Jr., CFO Joseph D. Dowling, and COO Michael Mona, III. See CVSI, 2017 Annual Report (Form 10-K), 2 (Mar. 30, 2018):

The Company’s first patent-pending product candidate, CVSI-007, combines CBD and nicotine in treatment of smokeless tobacco use and addiction. . . .CVSI-007 is based on proprietary formulations, processes and technology that we

believe are patent-protectable. In May 2016, we filed a patent application for these formulations and processes with the U.S. Patent and Trademark Office. We have a pending patent application for our product candidate CVSI-007 in the United States that will expire in 2036.

See CVSI, Annual Report (Form 10-K), 2 (Mar. 30, 2018).

68. This statement was misleading when made because the Company, Mona, Jr., Dowling, and Mona, III knowingly and/or recklessly made the statement while omitting the following facts:

- a. The USPTO issued the Final Rejection of CVSI-007's Patent Application and the Company was notified of the Final Rejection, which omissions: i) misled investors as to the true status of the Company's Patent Application; and 2) rendered Defendants' opinion that they believed CVSI-007 was "patent-protectable" misleading to a reasonable person reading the statement fairly and in context, especially considering the diminished likelihood of approval associated with the Final Rejection (*supra* ¶28);
- b. The Company lacked proprietary formulations, processes and technology as evidenced by the USPTO's Final Rejection which affirmed that CVSI-007 was "unpatentable" because it was an obvious invention; and

69. On May 14, 2018, in the Company's Quarterly Report which was signed by then-President and-CEO Mona, Jr. and CFO Dowling, the Company continued this con, stating:

Our specialty pharmaceutical business segment is developing synthetic cannabinoids to treat a range of medical conditions. ***The Company's product candidates are based on proprietary formulations, processes and technology that we believe are patent-protectable***, and we plan to vigorously pursue patent protection on the Company's two drug candidates.

See CVSI, Quarterly Report (Form 10-Q), 22 (May 14, 2018).

70. This statement was misleading when made because the Company, Mona, Jr., and Dowling knowingly and/or recklessly made the statement while omitting the following facts:

- a. The Company lacked proprietary formulations, processes, technology and lead drug candidate as evidenced by the USPTO's Final Rejection which affirmed that CVSI-007 was "unpatentable" because it was an obvious invention;

- b. The USPTO issued the Final Rejection of CVSI-007's Patent Application and the Company was notified of the Final Rejection, which omissions rendered the Company, Mona, Jr., and Dowling's opinion that they believed CVSI-007 was "patent-protectable" misleading to a reasonable person reading the statement fairly and in context, especially considering the diminished likelihood of approval associated with the Final Rejection (*supra* ¶28);

71. In a press release the next day, the Company and CFO Dowling continued this ruse, noting that there was "Continued Progress in Drug Development Division (original emphasis omitted) including preclinical progress with ***CVSI-007, the Company's patent pending synthetic-based cannabidiol***, which will be co-administered with nicotine to provide treatment options for smokeless tobacco use and addiction, currently a multibillion market with no currently FDA approved drugs available to help patients." See Press Release, *CV Sciences, Inc. Reports First Quarter 2018 Financial Results* (May 15, 2018). In this announcement, Dowling was quoted as having said, "[o]n the drug development side, we made steady progress in advancing CVSI-007 – our proprietary lead drug candidate - which addresses the multibillion dollar smokeless tobacco use and addiction market." *Id.*

72. This statement was misleading when made because the Company and Dowling knowingly and/or recklessly made the statement while omitting the following facts:

- a. The USPTO issued the Final Rejection of CVSI-007's Patent Application and the Company was notified of the Final Rejection, which omissions misled investors as to the true status of the Company's Patent Application, especially considering the diminished likelihood of approval associated with the Final Rejection (*supra* ¶28);
- b. The Company lacked a proprietary lead drug candidate as evidenced by the USPTO's Final Rejection which affirmed that CVSI-007 was "unpatentable" because it was an obvious invention; and
- c. The Company was not continuing to make steady progress in executing its drug development plan, which included the patenting of CVSI-007 (*supra* ¶39), given the USPTO's Final Rejection of CVSI-007's Patent Application and the Company's receipt of this Final Rejection; and,

- d. As a result, the Company's prospects for gaining market share in the "multibillion dollar smokeless tobacco use and addition market" were overstated given the diminished likelihood that the Company would ever be able to obtain a patent.

73. That same day on a conference call with investors, CFO Dowling emphasized this same point, stating, "***Our drug development segment continues to execute on our plan to develop the only FDA-approved drug to treat smokeless tobacco use and addiction.***" See CVSI, *Q1 2018 Earnings Call*, 2-3 (May 15, 2018) (transcript available through Bloomberg, L.P.). He went on to pump the drug's market potential, stating, "***CVSI believes strongly in the potential of our drug development program for the massive unmet need of treating nicotine use and addiction in multi-billion dollar market.***" *Id.*

74. This statement was misleading when made because the Company and Dowling knowingly and/or recklessly made the statement while omitting the following facts:

- a. The Company was not continuing to make steady progress in executing its drug development plan, which included the patenting of CVSI-007 (*supra* ¶39), given the USPTO's Final Rejection of CVSI-007's Patent Application and the Company's receipt of this Final Rejection; and
- b. The USPTO issued the Final Rejection of CVSI-007's Patent Application and the Company was notified of the Final Rejection, which omissions rendered the Company and Dowling's opinion that they believed "strongly in the potential of the drug development program" for a "multi-billion dollar market" misleading to a reasonable person reading the statement fairly and in context, especially considering the diminished likelihood of approval associated with the Final Rejection (*supra* ¶28).

75. On June 26, 2018, CEO and CFO Dowling continued this ruse in a letter to shareholders, noting "***Our proprietary patent-pending drug candidate (CVSI-007) combines synthetic CBD and nicotine and has the potential to effectively treat smokeless tobacco addiction. This treatment market has been estimated at greater than \$2 billion and provides another important growth channel for our Company.***" See CVSI, *Letter to Shareholders*, Current Report (Form 8-K) (June 26, 2018).

1 76. This statement was misleading when made because the Company and Dowling
2 knowingly and/or recklessly made the statement while omitting the following facts:

- 3 a. The USPTO issued the Final Rejection of CVSI-007's Patent Application and the
4 Company was notified of the Final Rejection, which omissions misled investors as to
5 the true status of the Company's Patent Application, especially considering the
6 diminished likelihood of approval associated with the Final Rejection (*supra* ¶28);
- 7 b. The Company lacked a proprietary drug candidate as evidenced by the USPTO's
8 Final Rejection which affirmed that CVSI-007 was "unpatentable" because it was an
9 obvious invention;
- 10 c. The Company was not continuing to make steady progress in executing its drug
11 development plan, which included the patenting of CVSI-007 (*supra* ¶39), given the
12 USPTO's Final Rejection of CVSI-007's Patent Application and the Company's
13 receipt of this Final Rejection; and,
- 14 d. As a result, the Company's prospects for gaining market share in the \$2 billion-dollar
15 market were overstated given the diminished likelihood that the Company would
16 ever be able to obtain a patent.

17 77. On August 1, 2018 in the Company's Quarterly Report for the Second Quarter of 2018,
18 which was signed by CEO and CFO Dowling, the Company and Dowling made identical statements to
19 those found in its Quarterly Report for the First Quarter of 2018 (*supra* ¶68). *See* CVSI, Quarterly
20 Report (Form 10-Q), 22 (Aug 1, 2018). This statement was misleading for the same reasons mentioned
21 above. *Supra* ¶70.

22 78. On August 1, 2018, the Company and Dowling issued a press release reporting its
23 financial and operating results for the second quarter of 2018 financial results. *See* Press Release, CV
24 Sciences, Inc. Reports Second Quarter 2018 Financial Results (Aug. 1, 2018). This press release
25 contained nearly identical misleading statements by the Company and Dowling regarding CVSI-007 as
26 those found in the Company's May 15, 2018 Press Release (*supra* ¶71). *Id.* These statements were
27 misleading for the same reasons mentioned above. *Supra* ¶72.

79. On August 23, 2018, the Company continued the scam, using a nearly identical slide from its earlier presentation on September 12, 2017 (*supra* ¶53). *See CVSI, CBD-Based Pharmaceutical & Consumer Products*, at 24 (Aug. 23, 2018). This slide again touted CVSI’s “*proprietary technology*” for its “*patent pending*” drug candidate.

80. This statement was misleading when made because the Company knowingly and/or recklessly made the statement while omitting the following facts:

- a. The USPTO issued the Final Rejection of CVSI-007’s Patent Application and the Company was notified of the Final Rejection, which omissions misled investors as to the true status of the Company’s Patent Application, especially considering the diminished likelihood of approval associated with the Final Rejection (*supra* ¶28); and
- b. The Company lacked proprietary technology as evidenced by the USPTO’s Final Rejection which affirmed that CVSI-007 was “unpatentable” because it was an obvious invention.

81. In summary, the statements in ¶¶61-80 were materially misleading when made because Defendants failed to disclose the material adverse fact that they received notice of the USPTO’s Final Rejection of CVSI-007’s Patent Application for being obvious and therefore “unpatentable.” As a result, CVSI significantly overstated the commercial viability of CVSI-007 and the likelihood that the Company could obtain a patent.

E. The Truth Is Revealed

82. The truth emerged on August 20, 2018 at 1:21 PM EST, when Citron Research issued a Tweet reporting on the USPTO’s two Rejections of CV Sciences’ Patent Application. It stated “\$CVSI misrepresentation by management. The total bull case is based on REJECTED patents the company has never disclosed and continues to hype.” A screenshot of this tweet, which included two relevant screenshots from the USPTO website, is included below:



83. This tweet gained traction as investors shared it via Twitter. At least one media outlet immediately reported on this information. See Matt Rego, *Bearish Tweet from Citron Research Craters Shares of CV Sciences, Inc.*, Spotlight Growth (Aug. 20, 2018), <http://spotlightgrowth.com/index.php/2018/08/20/bearish-tweet-from-citron-research-craters-shares-of-cv-sciences-inc-otcqb-cvsi/>. On this news, CV Sciences' share price plummeted from an intraday high of \$9.20 per share before the tweet to close at \$4.21 per share that same day. This was a decline of \$4.99 per share, or 54.24%. As a result of Defendants' wrongful acts and omissions, and the precipitous decline in the market value of CV Sciences' stock, Lead Plaintiff and other Class members have suffered significant losses and damages.

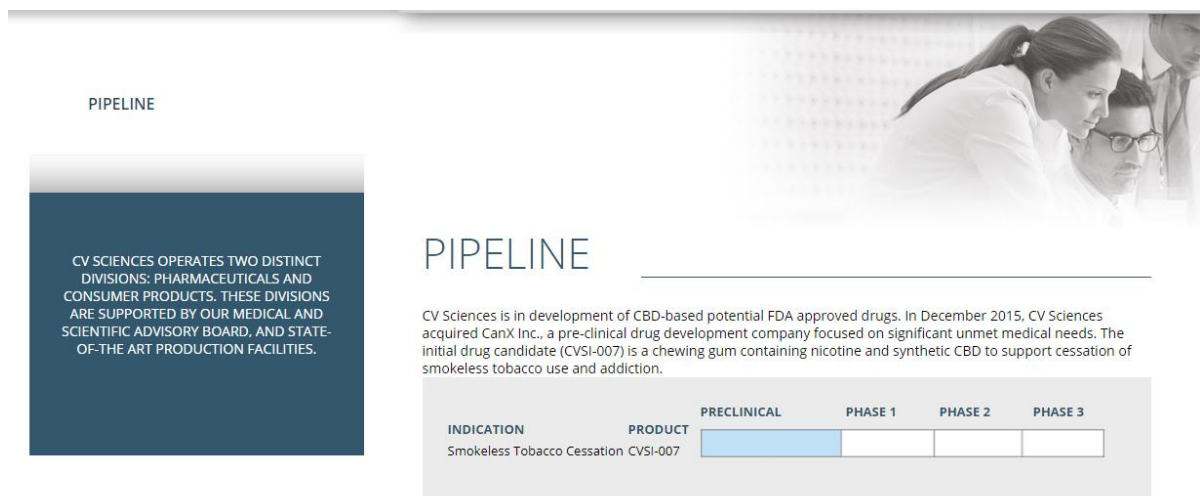
V. ADDITIONAL SCIENTER ALLEGATIONS

A. *Respondeat Superior* And Agency Principles Apply

84. CVSI is liable for the acts of CVSI's and any subsidiary's officers, directors, employees, attorneys, and agents under the doctrine of *respondeat superior* and common law principles of agency as all the wrongful acts complained of herein were carried out within the scope of their employment or agency with the authority or apparent authority to do so. The scienter of CVSI's officers, directors, employees, attorneys, and agents is similarly imputed to CVSI under *respondeat superior* and agency principles.

B. CVSI-007 Was A Core Product

85. Because the fraud alleged herein relates to the core business of CVSI, knowledge of the facts underlying the fraud may be imputed to the Individual Defendants. *See Reese v. Malone*, 747 F.3d 557 (9th Cir. 2014). This was the Company's leading pharmaceutical candidate. *See* 2017 Annual Report (Form 10-K), 2 (Mar. 30, 2018)). In fact, this is the Company's **only product** in its pharmaceutical pipeline currently listed on its website, of which a screenshot is included below. *See* CVSI, *Pipeline*, <https://cvsciences.com/pipeline/> (last accessed Jan. 4, 2018).



86. Furthermore, during the Class Period on March 26, 2018, there were only 52 full-time employees. *See* CVSI, Annual Report (Form 10-K) (Mar. 30, 2018). Therefore, the Individual Defendants, as senior level executives and/or directors, were in such positions at the Company to access all material, non-public information concerning the status of the CVSI-007 Patent Application.

87. In almost every earnings call with investors, the Company and Dowling discussed the progress of CVSI-007 development. *Supra* ¶¶55, 57, 61, 63, 73. Thus, the Individual Defendants understood their positive statements about the status of CVSI-007, made contemporaneously with knowledge of contradictory information, were materially misleading when made.

C. Individual Defendants Had Motive To Commit Fraud

88. For Mona, Jr., Mona, III, and Dowling, 1.5 million, 1 million, and 250,000 shares of Company stock vested, respectively, if the Company received “final meeting minutes from a pre-

1 investigational new drug application (‘IND’) meeting as authorized by the FDA for a drug development
2 program utilizing CBD as the active pharmaceutical ingredient.” *See* Forms 4 (Mar. 28, 2018).

3 89. These pre-IND meetings are part of a commonplace consultation program available to
4 potential IND holders to facilitate early communications with the FDA regarding an IND. *See*
5 University of Virginia, *Pre-IND Process*, [https://research.med.virginia.edu/clinicalresearch/protocol-](https://research.med.virginia.edu/clinicalresearch/protocol-manager/set-up-study/compliance/investigational-new-drug-ind/pre-ind-process/)
6 [manager/set-up-study/compliance/investigational-new-drug-ind/pre-ind-process/](https://research.med.virginia.edu/clinicalresearch/protocol-manager/set-up-study/compliance/investigational-new-drug-ind/pre-ind-process/). “The program allows
7 the sponsor-investigator the opportunity to discuss the proposed project and receive guidance directly
8 from the FDA prior to submitting an IND.” *Id. Therefore, Individual Defendants had a motive to*
9 *commit fraud as they had a specific, obscure condition that was easily satisfiable, even in the absence*
10 *of a Patent, but for which they wanted to keep the Company’s stock price high.*

11 90. Not surprisingly, the Individual Defendants easily satisfied this condition when “[d]uring
12 fiscal year 2017, the Company achieved the milestone of receiving the minutes from the Pre-
13 Investigational New Drug Application meeting held with the FDA in June 2017[.]” *See* 2017 Annual
14 Report (Form 10-K), F-25 (Mar. 30, 2018). When their shares vested during the Class Period, Mona,
15 Jr.’s shares were worth \$605,000, Mona, III’s shares were worth \$275,000, and Dowling’s shares were
16 worth \$110,000. *See* Forms 4 (Mar. 28, 2018).

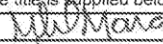
17 91. As such, Individual Defendants had a motive to make misleading statements pumping
18 CVSI’s development, even when they knew they had not — and could not — obtain a patent for CVSI-
19 007.

20 **D. Defendants Had Access To And Possession Of The USPTO’s Rejections Or Were**
21 **Deliberately Reckless In Failing To Correspond With Their Patent Counsel**

22 92. Defendants had access to and were in possession of adverse material facts regarding the
23 status of CVSI-007’s patent.

24 93. First, the Company retained Banner & Witcoff, Ltd., a leading patent law firm, to handle
25 all aspects of its CVSI-007 Patent Application. *See* Press Release, (Form 8-K), *Drug Development*
26 *Program and Overview*, Ex. 99.1, 15 (June 8, 2016). As part of their fiduciary and ethical duties,
27 attorneys at Banner & Witcoff undoubtedly kept Defendants up to date with the status of the Patent
28 Application and the USPTO’s two successive Rejections. As evidenced by their current, continued

representation of the Company, Banner & Witcoff sought Defendants' permission before filing: (1) a response to the First Rejection; (2) a Notice of Appeal after the Final Rejection; and (3) an Appeal Brief. *Supra* ¶¶43, 45. In fact, Mona, III granted Power of Attorney to Paul M. Rivard, Esq. of Banner and Witcoff. *See* USPTO, *Patent Application No. 15/426,617 Power of Attorney* (Feb. 7, 2017), <https://portal.uspto.gov/pair/PublicPair>. As such, Defendants knew about the USPTO's Rejections. Screenshots from these Power of Attorney documents are included below:

SIGNATURE of Applicant for Patent			
The undersigned (whose title is supplied below) is authorized to act on behalf of the applicant (e.g., where the applicant is a juristic entity).			
Signature		Date (Optional)	5/10/18
Name	Michael J. Mona, III		
Title	VP of Operations		
NOTE: Signature - This form must be signed by the applicant in accordance with 37 CFR 1.33. See 37 CFR 1.4 for signature requirements and certifications. If more than one applicant, use multiple forms.			
<input type="checkbox"/> Total of _____ forms are submitted.			

SIGNATURE of Applicant or Patent Practitioner			
Signature	/Paul M. Rivard/	Date (Optional)	February 7, 2017
Name	Paul M. Rivard	Registration Number	43,446

94. Second, in his August 1, 2018 call with shareholders, Dowling noted, “[t]here’s several questions about our drug development process.” *See* Joseph Dowling, Q2 2018 Earnings Call, 5 (Aug. 1, 2018) (transcript available through Bloomberg, L.P.). He then went on to deflect these questions, stating:

[W]e’re not in a position to provide any further information than what we have done so far. But we are making progress on our pre-clinical program. ***And for those that have experience in this area, it is a very thoughtful process. And we are going through that process very carefully. We will provide updates as appropriate.***

Id. If, as Dowling states, Defendants were truly conducting the pre-clinical process “carefully” or “thoughtfully,” they would necessarily have known about the USPTO’s Rejections.

95. Third, after the Class Period, and in response this action, Dowling admitted that he knew about the Final Rejection when he dismissed the validity of the claims by misleadingly stating that “[a] ‘final rejection’ in the context of patent prosecution is anything but final.” *See* CVSI, Press Release:

1 *CV Sciences Responds to Class Action Lawsuit* (Form 8-K) Ex. 99.1 (Aug 29, 2018). He further
 2 assured investors that, “[w]e will continue to prosecute the ‘617 Application and plan to file several
 3 more applications related to the inventions described in the ‘617 Application.” *Id.* These statements
 4 indicate that Dowling knew about the USPTO’s Rejections.

5 96. If the Defendants did not know about these Rejections, which is utterly implausible,
 6 then Defendants were deliberately reckless in not corresponding, monitoring, or following up with
 7 patent counsel, yet still making statements about the topic. *See Berson*, 527 F.3d at 987. “An actor is
 8 deliberately reckless if he had reasonable grounds to believe material facts existed that were misstated or
 9 omitted, but nonetheless failed to obtain and disclose such facts although he could have done so without
 10 extraordinary effort.”

11 **E. Mona, III Had Specialized Knowledge About The Patent Process**

12 97. The Company previously applied for a patent for a different CBD product on July 2,
 13 2014. U.S. Patent No. 9,340,475 (issued May 17, 2016). Its application for this patent was granted on
 14 May 17, 2016. *Id.* In fact, the patent application, which was never rejected by the USPTO, *listed*
 15 *Mona, III as the lead inventor*. As such, the Company and Mona, III were equipped with specialized
 16 knowledge about the patent approval process. Therefore, they knew the material significance of the
 17 USPTO’s two rejections of the Patent because their earlier patent had never been rejected.

18 **F. Fraud Is The *Modus Operandi* Of Mona, Jr. And The Company**

19 98. Mona, Jr. founded CannaVEST to profit off the hype surrounding marijuana stocks. *See*
 20 *Nathan Vardi, The First Pot Stock Billionaire Says His Penny Stock Could Be A Little High*, Forbes
 21 (Mar. 10, 2014). On June 16, 2017, the SEC charged him and the Company with fraud, filing false
 22 financial reports, and other federal securities law violations for overstating the value of an acquisition
 23 by \$27 million. *See SEC, Litigation Release No. 2386: SEC Charges Hemp Oil Company and CEO*
 24 *with Fraud*, (June 16, 2017) <https://www.sec.gov/litigation/litreleases/2017/lr23861.htm>; Nathan Vardi,
 25 *SEC Charges Poster Boy of Pot Penny Stock Bubble with Fraud*, Forbes (June 16, 2017). The SEC
 26 thereafter sought a permanent injunction and civil money penalties. *Id.*

27 99. The Company and Mona, Jr. ultimately entered a consent judgment with the SEC. *See*
 28 CVSI Press Release, *The Company Names New Chief Executive Officer, President and Board Member*

(June 1, 2018). This consent judgement included the payment of a penalty in the amount of \$150,000 by the Company. Additionally, Mona, Jr., agreed to a prohibition from serving as an officer or director of a publicly held company for five years and the payment of a penalty in the amount of \$50,000. *Id.*

The Company acknowledged this settlement, noting:

Effective concurrent with the settlement, Mr. Mona has resigned as the Company's President and Chief Executive Officer, and has resigned his position on the Company's Board of Directors. Joseph Dowling has been appointed as the Company's Chief Executive Officer, and will continue to serve as the Company's Chief Financial Officer. Mr. Dowling also has been appointed to the Company's Board of Directors. Michael J. Mona III has been appointed as the Company's President.

Id. Thumbing its nose at this judgment, the Company announced that it had re-hired Mona, Jr. on June 8, 2018 as "Founder-Emeritus" which was accompanied by a \$70,000 raise in annual salary. *See* CVSI, Current Report (Form 8-K) (June 14, 2018) (stating his updated \$400,000 salary); *cf.* CVSI, Proxy Statement (Schedule 14A), 12 (June 18, 2018) (stating his previous \$330,000 salary).

100. In the related parallel private class action case against the Company, the Court concluded that plaintiffs adequately alleged material misstatements and omissions, denying most of the Company's motion to dismiss. *See In re Cannavest Corp. Sec. Litig.*, 307 F. Supp. 3d 222, 231–32 (S.D.N.Y. 2018) (J. Gardephe). Mona, Jr. was a named Defendant in this case, and, in any event, this confirms that Defendants were well aware of their disclosure obligations to investors.

G. SOX Certifications

101. Individual Defendants Mona, Jr. and Dowling signed certifications pursuant to the Sarbanes-Oxley Act of 2002 ("SOX") which they filed with the SEC in connection with the filing of CVSI's March 30, 2018 Annual Report ("Form 10-K") for 2017. They certified that their report "fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934" and that the information contained therein "fairly presents, in all material respects, the financial condition and results of operations of the Registrant." *Id.* at Exs. 32.1 (Mona, Jr.'s certification), 32.2 (Dowling's certification). Mona, Jr. and Dowling further certified that they each "reviewed this Annual Report on Form 10-K of the Company" and:

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

Id. at Ex. 31.1 (Mona, Jr.'s certification), 32.1 (Dowling's certification).

102. Individual Defendants Mona, Jr. and Dowling signed certifications pursuant to SOX that they filed with the SEC in connection with the filing of CVSI's Quarterly Reports ("**Forms 10-Q**") on: (1) August 11, 2017 for the Second Quarter of 2017; (2) November 8, 2017 for the Third Quarter of 2017, and; (3) May 14, 2018 for the First Quarter of 2018. These Reports certified that they each "reviewed this Quarterly Report on Form 10-Q of the Company" and contained identical certifications to those found in the Annual Report (*supra* ¶101). *See* respective Quarterly Reports at Exs. 31.1, 32.1 (Mona, Jr.'s certifications), Exs. 31.2, 32.2 (Dowling's certifications).

103. After Mona, Jr. was forced to resign pursuant to his SEC deal, Individual Defendant Dowling signed certifications pursuant to SOX which he filed with the SEC in connection with the filing of CVSI's Quarterly Report on August 1, 2018 for the Second Quarter of 2018. *See* CVSI, Quarterly Report (Form 10-Q), 22 (Aug 1, 2018). This Report certified that Dowling "reviewed this Quarterly Report on Form 10-Q of the Company" and contained identical certifications to those found in the Annual Report (*supra* ¶101). *See Id.* at Exs. 31.1, 32.1 (Dowling's certifications).

VI. CLASS ACTION ALLEGATIONS

104. Lead Plaintiff brings this action pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of himself, as trustee, and a class consisting of all persons and entities who purchased CVSI common stock in the United States or on the OTC between June 19, 2017 and prior to August 20, 2018 at 1:21 PM, inclusive, and who were damaged thereby (the "**Class**").

105. Excluded from the Class are Defendants, the officers and directors of CVSI at all relevant times, members of their immediate families and their legal representatives, heirs, agents, affiliates, successors or assigns, Defendants' liability insurance carriers, and any affiliates or

1 subsidiaries thereof, and any entity in which Defendants or their immediate families have or had a
2 controlling interest.

3 106. Also excluded from the Class are those who purchased CVSI common stock on foreign
4 exchanges or purchased CVSI common stock outside of the United States, in accordance with the
5 United States Supreme Court's decision in *Morrison v. Nat'l Australia Bank Ltd.*, 561 U.S. 247, 267
6 (2010) ("[I]t is in our view only transactions in securities listed on domestic exchanges, and domestic
7 transactions in other securities, to which § 10(b) applies.").

8 107. The members of the Class are so numerous that joinder of all members is impracticable.
9 During the Class Period, CVSI common stock was actively traded on the OTC, which was an efficient
10 market. The exact number of Class members cannot be determined at this early stage, Lead Plaintiff
11 believes that thousands of people held CVSI common stock during the Class Period. Record owners
12 and other members of the Class may be identified from records maintained by CVSI or its transfer agent
13 and may be notified of the pendency of this action by mail, using a form of notice like that customarily
14 used in securities class actions.

15 108. Lead Plaintiff's claims are typical of the claims of the other members of the Class
16 because Lead Plaintiff and all members of the Class were similarly affected by Defendants' unlawful
17 conduct as complained of herein.

18 109. Lead Plaintiff will fairly and adequately protect the interests of the Class and has
19 retained counsel competent and experienced in class action and securities litigation. Lead Plaintiff has
20 no interests that are contrary to or in conflict with those of the Class.

21 110. Common questions of law and fact exist as to all members of the Class, and predominate
22 over any questions solely affecting individual members of the Class. The questions of law and fact
23 common to the Class include, *inter alia*:

- 24 a. Whether the federal securities laws were violated by Defendants' acts as alleged
25 herein;
- 26 b. Whether Defendants' publicly disseminated statements made during the Class Period
27 omitted to state material facts necessary in order to make the statements made, in
28 light of the circumstances under which they were made, not misleading;

- c. Whether and to what extent Defendants' omissions of material fact caused the market price of CVSI's common stock to be artificially inflated during the Class Period;
- d. Whether Defendants acted with the requisite level of scienter in omitting material facts when they made misleading statements;
- e. Whether the Individual Defendants were controlling persons of CVSI; and
- f. Whether the Class members have sustained damages, and, if so, the proper measure of damages.

111. Lead Plaintiff knows of no difficulty that will be encountered in the management of this action that would preclude its maintenance as a class action.

112. A class action is superior to all other available methods for the fair and efficient adjudication of this action because, among other things, joinder of all members of the Class is impracticable. In addition, since the damages suffered by individual members of the Class may be relatively small, the expense and burden of individual litigation would make it nearly impossible for members of the Class to bring individual actions.

VII. LOSS CAUSATION

113. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated CVSI's stock price and operated as a fraud or deceit on Class Period purchasers of CVSI common stock by misrepresenting the Company's business and prospects. During the Class Period, Defendants misled investors regarding the commercial viability of CVSI-007 by failing to disclose the USPTO's Rejections. *Supra* ¶¶46-81. As a result of their purchases of CVSI common stock during the Class Period at artificially inflated prices, Lead Plaintiff and other Class members suffered damages when the truth was revealed.

114. The correct test for loss causation is a general proximate cause test. *Mineworkers' Pension Scheme v. First Solar Inc.*, 881 F.3d 750 (9th Cir. 2018). Therefore, to prove loss causation, plaintiffs need only show a "causal connection" between the fraud and the loss. *Id.* at 753. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the damages suffered by Lead Plaintiff and the Class. This is clear from the fact that after the Citron Research tweet disclosing this

1 fraud was issued, the stock price of CVSI plummeted \$4.99 from its intraday high, or 54.24%, per
2 share.

3 115. Defendants' misleading statements and omissions in their SEC filings and other public
4 statements during the Class Period directly and proximately caused damages to Lead Plaintiff and the
5 Class. On the strength of these misleading statements, the Company's stock price was artificially
6 inflated to \$9.20 per share on August 20, 2018. Those misleading statements and omissions that were
7 not immediately followed by an upward movement in the Company's stock price served to maintain the
8 share price at artificially inflated levels. The allegations herein suffice under a general proximate cause
9 theory, a corrective disclosure theory, and a materialization of the risk theory of loss causation.

10 116. As relevant here, CVSI's stock dropped after Citron Research tweeted about the status of
11 its CVSI-007 patent. This drop and its accompanying disclosure satisfies the corrective disclosure
12 theory either alone or together with other disclosures because it revealed some aspect of the truth to the
13 market regarding, *inter alia*, the failure and difficulties of its pharmaceutical division to patent its sole
14 product, and consequently removed the artificial inflation in CVSI's stock price and directly and
15 proximately caused Lead Plaintiff and the other Class members to suffer damages. *Supra* ¶82. The
16 drop occurred on August 20, 2018 and CVSI's common stock fell \$4.99 per share from an intraday high
17 of \$9.20 per share on August 20, 2018 to a close of \$4.21 per share on August 20, 2018, a drop of
18 approximately 54.24%. *Supra* ¶83.

19 117. The aforementioned disclosures also suffice under the materialization of the risk theory
20 of loss causation because Defendants' misleading statements and omissions in their SEC filings and
21 other public statements during the Class Period (*supra* ¶¶46-81) concealed the risks attendant to the fact
22 that the USPTO had twice rejected the Company's Patent Application for CVSI-007 (*supra* ¶¶41, 44).

23 **VIII. CONTROL PERSON LIABILITY**

24 118. The Individual Defendants, because of their positions with CVSI, possessed the power
25 and authority to control the contents of CVSI's reports to the SEC, press releases, and presentations to
26 securities analysts, money and portfolio managers, and institutional and other investors. Each of the
27 Individual Defendants had a duty to (1) promptly disseminate complete, accurate, and truthful
28 information about the commercial viability of CVSI-007, specifically those facts concerning the

Rejections of CVSI-007's Patent Application; (2) correct any previously issued statements that were materially misleading or untrue when made so that the market could accurately price the Company's stock based upon truthful, accurate, and complete information; and (3) update any previously-issued forward-looking statements that became materially misleading or untrue so that the market could accurately price the Company's securities based upon truthful, accurate, and complete information. Each of the Individual Defendants was provided with copies of the Company's reports and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of the Individual Defendants knew that the adverse facts and omissions specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations and omissions which were being made were then materially misleading.

IX. THE FRAUD ON THE MARKET PRESUMPTION

119. At all relevant times, the market for CVSI's common stock was an efficient market for the following reasons, among others:

- a. CVSI's common stock was listed and actively traded on the OTC Market Exchange (symbol CVSI), an efficient market;
- b. As a registered and regulated issuer of securities, CVSI filed periodic reports with the SEC, in addition to the frequent voluntary dissemination of information;
- c. CVSI regularly communicated with public investors through established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services and through other wide-ranging public disclosures such as communications with the financial press and other similar reporting services;
- d. The market reacted to public information disseminated by CVSI;
- e. The materially misleading statements and omissions alleged herein would tend to induce a reasonable investor to overvalue CVSI's stock; and

f. Without knowledge of the omitted facts, Lead Plaintiff and other members of the Class purchased CVSI common stock between the time that the Defendants made the materially misleading statements and omissions and the time that the truth was revealed, during which time the price of CVSI common stock was artificially inflated by Defendants' misleading statements and omissions.

120. As a result of the above, the market for CVSI stock promptly digested current, reasonably available information with respect to the Company from all public sources and reflected such information in the stock's prices. The historical daily trading prices and volumes of CVSI stock are incorporated herein by reference. Under these circumstances, all those who purchased CVSI stock during the Class Period suffered similar injuries through their purchases of common stock at prices which were artificially inflated by Defendants' misleading statements and omissions. A presumption of reliance therefore applies.

X. THE AFFILIATED UTE PRESUMPTION

121. At all relevant times, Plaintiff and the Class reasonably relied upon Defendants to disclose material information as required by law and in the Company's SEC filings. Plaintiff and the Class would not have purchased or otherwise acquired CVSI stock at artificially inflated prices if Defendants had disclosed all material information as required. Thus, to the extent Defendants wrongfully failed to disclose material information concerning the Rejections and the resulting: (a) diminished likelihood of USPTO approval of the Patent Application; (b) stalled or delayed status of the Patent Application, and/or; (c) decreased or delayed revenue prospects for CVSI-007, Plaintiff is presumed to rely on Defendants' omissions as established by the Supreme Court in *Affiliated Ute Citizens v. U.S.*, 406 U.S. 128 (1972). See *In re Volkswagen "Clean Diesel" Mktg., Sales Practices, & Prod. Liab. Litig.*, No. MDL 2672 CRB (JSC), 2019 WL 4727338, at *1 (N.D. Cal. Sept. 26, 2019).

XI. NO STATUTORY SAFE HARBOR

122. The safe harbor provisions for forward-looking statements under the Private Securities Litigation Reform Act of 1995 are applicable only under certain circumstances that do not apply to any of the materially misleading statements and omissions alleged in this Complaint.

123. First, the identified misleading statements and omissions herein are not forward-looking

statements, but instead are statements of current or historic fact or statements of the speaker's then-existing opinion, or are actionable in context because they omit then-existing material facts.

124. Second, many, if not all, of the identified misleading statements herein were not identified as forward-looking statements.

125. Third, to the extent there were any forward-looking statements that were identified as such at the time made, there were no meaningfully cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Such statements were also not accompanied by cautionary language that was meaningful because any such warnings or "risk" factors contained in, or incorporated by reference in, the relevant press release, SEC filings, earnings call, or other public statement described herein were general, "boilerplate" statements of risk that would affect any pharmaceutical company, and misleadingly contained no factual disclosure of any of the specific details concerning the Rejections or similar important factors that would give investors adequate notice of such risks.

126. Fourth, to the extent there were any forward-looking statements, Defendants are liable for those misleading forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was, by reason of what the speaker failed to note, materially misleading, and/or that each such statement was authorized and/or approved by a director and/or executive officer of CVSI who actually knew that each such statement was misleading when made.

XII. CAUSES OF ACTION

COUNT I

Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

127. Lead Plaintiff re-alleges each allegation above as if fully set forth herein.

128. This Count is brought under Section 10(b) of the Exchange Act (15 U.S.C. § 78j(b)), and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5), against all Defendants.

129. During the Class Period, Defendants violated Section 10(b) and Rule 10b-5 in that they: (a) employed devices, schemes, and artifices to defraud; (b) made statements while failing to disclose material facts necessary in order to make the statements made, in light of the circumstances under

1 which they were made, not misleading; and/or (c) engaged in acts, practices, and a course of business
2 that operated as a fraud or deceit upon Lead Plaintiff and others similarly situated in connection with
3 their purchases of CVSI common stock during the Class Period.

4 130. Defendants, individually and in concert, directly and indirectly, by use of means or
5 instrumentalities of interstate commerce and/or of the mails made the misleading statements specified
6 herein, including the statements in SEC filings, presentations, press release, and conference calls
7 regarding the commercial viability of CVSI-007 as related to the USPTO's Rejections of CVSI-007's
8 Patent Application, whose truth they knowingly or recklessly disregarded when they failed to disclose
9 material facts necessary to make the statements made, in light of the circumstances under which they
10 were made, not misleading.

11 131. Defendants, individually and in concert, directly and indirectly, by use of means or
12 instrumentalities of interstate commerce and/or of the mails, employed devices, schemes, and artifices
13 to defraud and engaged and participated in a continuous course of conduct to conceal the USPTO's
14 rejection of CVSI-007's Patent Application and its implications for the Company.

15 132. Defendants acted with scienter throughout the Class Period because each acted with
16 either the intent to deceive, manipulate, or defraud, or with deliberate recklessness. Defendants
17 possessed actual knowledge of the misleading statements and omissions of material facts set forth
18 herein, or acted with reckless disregard for the truth by failing to ascertain and to disclose such facts
19 even though such facts were available to them, or deliberately refrained from taking steps necessary to
20 discover whether the statements were materially misleading.

21 133. CVSI is liable for the acts of the Individual Defendants and other Company agents and
22 personnel referenced herein under the doctrine of *respondeat superior*, as those persons were acting as
23 the officers, directors, attorneys and/or agents of CVSI in taking the actions alleged herein.

24 134. Lead Plaintiff and Class Members purchased CVSI common stock, without knowing that
25 Defendants -made materially misleading statements by omitting material facts about the Company's
26 operations and financial performance or prospects. In so doing, Lead Plaintiff and Class members
27 relied on misleading statements made by Defendants, and/or an absence of material adverse information
28

that was known to Defendants or recklessly disregarded by them but not disclosed in Defendants' public statements.

135. Lead Plaintiff and other Class members have suffered damages in that, in direct reliance on the integrity of the market, they paid artificially inflated prices for CVSI common stock, which inflation was removed from the prices of their shares when the true facts became known. Lead Plaintiff and the Class would not have purchased CVSI common stock at the prices they paid, or at all, if they had been aware that the market price had been artificially and misleadingly inflated by Defendants' materially misleading statements.

136. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiff and other Class members suffered damages in connection with their purchases of CVSI common stock during the Class Period when the truth was revealed.

COUNT II

Violations of Section 20(a) of the Exchange Act Against the Individual Defendants

137. Lead Plaintiff re-alleges each allegation above as if fully set forth herein.

138. This Count is asserted against the Individual Defendants for violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), on behalf of all members of the Class.

139. During their tenures as officers and/or directors of CVSI, each of the Individual Defendants acted as controlling persons of CVSI within the meaning of Section 20(a) of the Exchange Act. By reason of their status as senior executive officers and/or directors of CVSI, the Individual Defendants had the power and authority to direct the management and activities of the Company and its employees, and to cause the Company to engage in the wrongful conduct complained of herein. Each of the Individual Defendants was able to and did control, directly and indirectly, the content of the public statements made by the Company during the Class Period, including the statements Lead Plaintiff alleges are misleading, thereby disseminating the misleading statements and omissions of fact alleged herein.

140. By virtue of their high-level positions at CVSI, and as more fully described above, each of the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company. The Individual Defendants were able to and did influence and control CVSI's decision-

making, including reviewing and controlling the content and dissemination of the documents that Lead Plaintiff and the Class contend contained materially misleading information and on which Lead Plaintiff and the Class relied. The Individual Defendants were also in the position to prevent the issuance of these statements or to correct them prior to and after dissemination.

141. As set forth in Count I, CVSI committed a primary violation of Section 10(b) of the Exchange Act by knowingly and/or recklessly employing devices, artifices, and schemes to defraud, disseminating materially misleading statements and/or omissions, and/or engaging in acts, practices, or a course of conduct that operated as a fraud or deceit upon Lead Plaintiff and the Class throughout the Class Period. By virtue of their positions as controlling persons of CVSI and as a result of their own aforementioned wrongful conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act, jointly and severally with, and to the same extent as the Company is liable under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

142. As a direct and proximate result of the Individual Defendants' wrongful conduct, Lead Plaintiff and the Class suffered damages in connection with their purchases of CVSI common stock when the truth was revealed.

XIII. JURY TRIAL DEMAND

143. Lead Plaintiff hereby demands a trial by jury on all triable claims.

XIV. PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiff demands judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Lead Plaintiff as the Class representative;

B. Requiring Defendants to pay damages sustained by Lead Plaintiff and the Class by reason of the acts and statements alleged herein;

C. Awarding Lead Plaintiff and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees, and other costs; and

D. Awarding rescissory damages in favor of Lead Plaintiff and the other Class members where appropriate against all Defendants, jointly and severally, for all injuries sustained as a result of Defendants' wrongdoing, in an amount to be determined at trial, including pre-judgment and post-

judgment interest, as allowed by law;

E. Awarding such other and further relief as this Court may deem just and proper.

Dated: March 5, 2021

By: /s/ Richard W. Gonnello
Richard W. Gonnello

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*Attorneys for Lead Plaintiff Richard Ina, as
Trustee for The Ina Family Trust and Lead
Counsel for the Class*

CERTIFICATE OF SERVICE

I hereby certify that on March 5, 2021, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to counsel of record.

By: /s/ Richard W. Gonnello
Richard W. Gonnello